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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION,  
and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

**PLAINTIFFS' OPPOSITION TO  
DEFENDANT'S MOTION FOR PARTIAL  
SUMMARY JUDGMENT OF INVALIDITY  
(\*142 PATENT, CLAIMS 1 AND 8)**

Date: June 25, 2008

Time: 2:00 PM

Room: Courtroom 6, 4th Floor

Judge: Hon. Ronald M. Whyte

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1 Plaintiffs Hologic, Inc., Cytac Corporation, and Hologic L.P. (collectively, “Hologic”)  
2 respectfully submit this Memorandum in Opposition to Defendant’s Motion for Partial Summary  
3 Judgment of Invalidity of Claims 1 and 8 of the ’142 patent (the “Motion”).

4 **I. PRELIMINARY STATEMENT**

5 SenoRx’s motion relies entirely on a flawed construction of claim 1 of the ’142 patent. Indeed,  
6 as set forth in Hologic’s *Markman* briefing, [see Docket Items (“D.I.”) # 134, 144], SenoRx’s proposed  
7 construction of the term “apparatus volume” improperly isolates select words of the claim from the  
8 context of the claim as a whole, and divorces their meaning from the specification and prosecution  
9 history. Under a correct construction as proposed by Hologic, claims 1 and 8 define an operable and  
10 enabled invention, as the Court suggested during the Preliminary Injunction proceedings. As such,  
11 SenoRx’s incorrect claim construction should be rejected and its present Motion denied.

12 **II. THE ’142 PATENT**

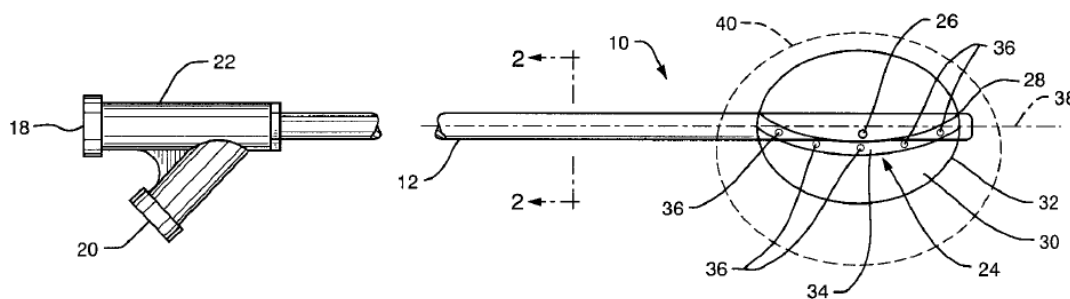
13 The ’142 patent discloses and claims an interstitial brachytherapy device by which users have  
14 “the ability to shape the radiation dose to protect sensitive tissue.” ’142 Patent, 2:49-50. The device  
15 “shapes” the radiation dose by “delivering radioactive emissions in an asymmetric fashion to target  
16 tissue surrounding a surgical extraction site,” for example, following the extraction of a cancerous  
17 lump from the breast. *Id.* at 2:57-59. By “locating the radiation source so as to be asymmetrically  
18 placed with respect to a longitudinal axis of the” device, “an isodose profile [may be produced] in the  
19 target tissue that is asymmetric about the longitudinal axis of the apparatus.” *Id.* 2:65-3:6.

20 The invention encompassed in claim 1<sup>1</sup> includes “an expandable outer surface element defining  
21 a three-dimensional apparatus volume.” ’142 Patent, 8:63-64 (claim 1). As recited in claim 1, the  
22 apparatus volume in question is composed of (i.e., “defin[ed]” by) an expandable outer surface  
23 element, which has any number of embodiments. For example, the specification discloses that the  
24 apparatus volume may be defined by “an outer polymeric film barrier” or it could be “an expandable  
25 cage, formed from a shape memory metal, . . . or a suitable plastic.” ’142 Patent, 4:28-29 and 4:39-42.

26  
27 \_\_\_\_\_  
28 <sup>1</sup> Claim 8 depends from claim 1 and, therefore, includes all of the elements recited in claim 1.

Thus, there are any number of embodiments of the expandable outer surface element that can define the apparatus volume.

A radiation source is provided within the three dimensional apparatus volume composed of the expandable outer surface element. By asymmetrically placing the radiation source with respect to the longitudinal axis of the device, asymmetric isodose profiles can be created to “shape” the radiation dose provided to the tissue surrounding the resection. An exemplary embodiment of the device including an expandable outer surface element is shown in Figure 1 (reproduced below).



It must be noted that, in every embodiment disclosed in the specification, the radiation source is placed **within** the three dimensional apparatus volume. SenoRx construction of the claims would require that the radiation source be **outside** the three dimensional apparatus volume. This is not only nonsensical and contrary to the clear teachings of the specification, but it would also exclude all of the embodiments in the specification, including the preferred ones, from satisfying the claims.

### III. ARGUMENT

#### A. SenoRx Cannot Show That There Are No Genuine Factual Disputes

Summary judgment is appropriate only when there are no genuine issues of material fact and the movant demonstrates that they are entitled to judgment as a matter of law. *See* FED. R. CIV. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Council of Ins. Agents & Brokers v. Molasky-Arman*, 522 F.3d 925, 930 (9th Cir. 2008). “The movant carries the initial burden of proving that there are no genuine issues of material fact.” *Air Turbine Tech., Inc. v. Atlas Copco AB*, 410 F.3d 701, 707-08 (Fed. Cir. 2005) (citing *Celotex*, 477 U.S. at 322-24). “[I]n ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive

evidentiary burden,” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986), which, for patent invalidity is the **clear and convincing** evidentiary standard, *see* 35 U.S.C. § 282 (2006); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

Only when the movant properly supports its motion for summary judgment must “the adverse party . . . ‘set forth specific facts showing that there is a genuine issue for trial.’” *Id.* at 250 (quoting FED. R. CIV. P. 56(e)(2)). Thus, while

[i]t is true that a party opposing summary judgment “must ... set out specific facts showing a genuine issue for trial[,]” Fed.R.Civ.P. 56(e)(2)[,] . . . that is only true where the movant’s “motion for summary judgment is properly made and supported”—i.e., where the movant has otherwise established entitlement to judgment as a matter of law. *Id.* “A non-movant need not always provide affidavits or other evidence to defeat a summary judgment motion. If, for example, the movant bears the burden and its motion fails to satisfy that burden, the non-movant is ‘not required to come forward’ with opposing evidence.” *Saab Cars USA, Inc. v. United States*, 434 F.3d 1359, 1368 (Fed. Cir. 2006) (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 160, 90 (1970) (citing the advisory committee’s note to Federal Rule of Civil Procedure 56(e))).

*Zenith Elecs. Corp. v. PDI Commc’n Sys., Inc.*, 522 F.3d 1348, 1363 (Fed. Cir. 2008).

SenoRx’s Motion is facially deficient because it is not supported by *any facts*. It consists of only lawyers’ argument with no supporting affidavits from an expert or otherwise.<sup>2</sup> Lawyers’ arguments are not evidence. *See, e.g., C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 674 n.2 (Fed. Cir. 1990) (“Of course, argument by counsel does not constitute evidence.”); *cf. Watts v. United States*, 703 F.2d 346, 353 (9th Cir. 1983) (“Legal memorandum and argument are not evidence and cannot, by themselves, create a factual dispute sufficient to defeat summary judgment where no dispute otherwise exists.”). Yet, SenoRx acknowledges that the question of whether a claimed invention is operable presents factual issues. [See D.I. #133 (SenoRx’s Motion for Partial Summary Judgment of Invalidity (’142 Patent, Claims 1 and 8)) at 3 (“Utility is a question of fact . . . . Lack of enablement is . . . based on underlying factual inquiries.”).] Hologic agrees with SenoRx in

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<sup>2</sup> SenoRx supports its entire motion on the declaration of one of its attorneys, Mr. Harber. Mr. Harber’s declaration is limited to authenticating a copy of the ’142 Patent appended to its papers. [See Docket Item (“D.I.”) 133-2 (Harber Decl.) ¶ 1.]

that regard. *See, e.g., id.* (citing cases); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (noting that in cases where operability is an issue, questions of utility and enablement may turn on the same underlying facts). SenoRx’s failure to present any evidence—let alone *clear and convincing evidence*—of invalidity of claims 1 and 8 of the ’142 patent, requires denial of its Motion.<sup>3</sup>

#### **B. SenoRx Cannot Carry Its Substantive Burden On The Merits**

Three legal principles make it impossible for SenoRx to carry its burden of establishing invalidity of claims 1 and 8. First, as with all patent cases, SenoRx must prove that the claims it seeks to invalidate are invalid by clear and convincing evidence. *See* 35 U.S.C. § 282 (2006); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). Second, SenoRx must overcome the strong presumption that the claims encompass the preferred embodiments. *See, e.g., Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008) (“At lease [sic least] where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment . . . .”); *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996); *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996) (“We share the district court’s view that it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.”); *Modine Mfg. Co. v. United States Int’l Trade Comm’n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996) (“[A] claim interpretation that would exclude the inventor’s device is rarely the correct interpretation; such an interpretation requires highly persuasive evidentiary support.”). “It is elementary that a claim construction that excludes the preferred embodiment is rarely, if ever correct.” *NeoMagic*, 287 F.3d at 1074 (internal quotation omitted). Thus, an interpretation that would exclude all of the preferred

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<sup>3</sup> Moreover, because SenoRx has failed to present any evidence to support its motion, Hologic is under no obligation to establish that there are genuine issues of material fact requiring a trial. *See Saab Cars USA*, 434 F.3d at 1368 (“A non-movant need not always provide affidavits or other evidence to defeat a summary judgment motion. If, for example, the movant bears the burden and its motion fails to satisfy that burden, the non-movant is ‘not required to come forward’ with opposing evidence.”).



embodiments “requires highly persuasive evidentiary support.” Third, SenoRx must demonstrate that the claim language unambiguously warrants a conclusion of invalidity; an ambiguous claim may be construed to preserve its validity if doing so is not inconsistent with the intrinsic evidence. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc) (“[W]e have limited the maxim to cases in which ‘the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.’” (quoting *Libel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004))). SenoRx cannot overcome these hurdles.

### C. SenoRx’s Motion Is Predicated On An Improper Claim Construction

SenoRx’s unsupported attorney arguments regarding invalidity rest on an utterly implausible claim construction. As Hologic explained in its claim construction briefing, [*see* D.I. #134 at 22-24; D.I. #144 at 16-20], SenoRx’s claim construction violates the most fundamental principles of claim construction. SenoRx’s construction: (1) improperly excludes all of the disclosed embodiments, *see Oatey Co.*, 514 F.3d at 1277; *NeoMagic*, 287 F.3d at 1074; *Vitronics*, 90 F.3d at 1583; *Hoechst Celanese Corp.*, 78 F.3d at 1581; *Modine Mfg. Co. v. United States Int’l Trade Comm’n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996); and (2) ignores the principle that where the claim terms may be ambiguous after resorting to the intrinsic record, they may be construed to preserve their validity, *see Phillips v. AWH Corp.*, 415 F.3d at 1327. *See also Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371, 1376 (Fed. Cir.), *vacated and remanded on other grounds*, 537 U.S. 802 (2002) (“We agree that a construction that renders the claimed invention inoperable should be viewed with extreme skepticism.”).

SenoRx’s claim construction rests primarily on a definition of “volume” that imposes a rigid, literal interpretation of the claim language, divorced from the context of the specification. Such an approach is unquestionably improper. Indeed, when the words surrounding the term “volume” (e.g., “apparatus,” “three-dimensional,” “defining,” and “expandable outer surface”) are considered, *see, e.g., ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“[T]he context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms.”), the term “three-dimensional apparatus volume configured to fill an

1 interstitial void . . . and define an inner boundary of the target tissue being treated,” is properly  
 2 construed to mean that the three-dimensional apparatus volume is composed of an expandable outer  
 3 surface. This is the interpretation that best comports with the specification and the inventor’s  
 4 understanding of the claims. *See Phillips*, 415 F.3d at 1315 (“[T]he specification is always highly  
 5 relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the  
 6 meaning of a disputed term.” (internal quotations and citations omitted)). Thus, as discussed in detail  
 7 in Hologic’s claim construction briefing, SenoRx’s proposed claim construction should be rejected.  
 8 SenoRx’s improper claim construction alone merits denial of SenoRx’s motion.

#### 9 **D. The Cases Relied On By SenoRx Are Distinguishable**

10 SenoRx slavishly relies on a line of cases that invalidated unambiguous claims, a situation that  
 11 is distinct from the case at bar, which involves an ambiguous claim term (that hence warrants  
 12 construction). Two of the primary cases relied on by SenoRx – *Chef America* and *Process Control*<sup>4</sup> –  
 13 were recently distinguish by the Federal Circuit in *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*,  
 14 520 F.3d 1358, 1361 (Fed. Cir. 2008). In *Ortho*, the court held that the word “and,” as used  
 15 in a claim meant “or.” *Id.* (“[T]his court sustains the trial court’s ruling that, in the circumstances of  
 16 this case, claim 1’s use of the term *and* means *or*.” (emphasis in original)). In reaching this result, it  
 17 read the term “and,” not simply in isolation, “but in [the] larger context that clarifies its meaning”  
 18 within the claim. *Id.* at 1362. The Federal Circuit distinguished *Process Control* and *Chef America*:

19 *Chef America* does not require this court or the district court to interpret *and*  
 20 according to its most common usage in the dictionary. To the contrary, this court  
 21 and the district court must interpret the term to give proper meaning to the claim  
 22 in light of the language and intrinsic evidence. Giving *and* its most common  
 23 dictionary meaning would produce in this case the nonsensical result of not  
 24 covering topiramate and rendering several other dependent claims meaningless.  
 In *Chef America*, the only possible interpretation of the claim led to a nonsensical  
 result. This situation is distinguishable because claim 1 can and should be  
 interpreted as the patentees intended, with the meaning of *and* connoting  
 alternatives.

25 *Ortho-McNeil*, 520 F.3d at 1362-63.

26 \_\_\_\_\_  
 27 <sup>4</sup> *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1376 (Fed. Cir. 2004); *Process Control*  
 28 *Corp. v. HydReclaim Corp.*, 190 F.3d 1350 (Fed. Cir. 1999)

Thus, the *Chef America* case is distinguishable from the present case. First, *Chef America* was not a case in which the accused infringer sought to invalidate the claims. Rather, it was appealed on the question of infringement only. *Chef America*, 358 F.3d at 1376. Second, the claim language at issue in *Chef America* was unambiguous. The patentee was attempting to read the claim language “heating the resulting . . . dough to a temperature in the range of about 400°F to 850°F,” as “heating the . . .” oven to the claimed temperature. *Chef America*, 358 F.3d at 1372. Thus, as the Federal Circuit stated in *Ortho*, “[i]n *Chef America*, the only possible interpretation of the claim led to a nonsensical result.” In this case, by contrast, SenoRx’s strained construction is not “the only possible interpretation,” and indeed, is not the most correct interpretation.

Likewise in both *Allen Engineering Corp. v. Bartell Industries, Inc.*, 299 F.3d 1336, 1348-49 (Fed. Cir. 2002), and *Process Control*, the language used in the claim was unambiguous. In *Allen Engineering*, the patentee asked the court to construe “perpendicular” as “parallel.” 299 F.3d at 1348-49. In *Process Control*, the patentee attempted to impose on the claim a meaning that the claim simply was not susceptible to. 190 F.3d at 1356-57. The Federal Circuit rejected both attempts. *Id.* at 1356 (“[T]his is not a case where the claim language is reasonably susceptible to two constructions. Rather, the claim as written by the patentee is susceptible to only one meaning.”).

Unlike *Chef America*, *Allen Engineering*, and *Process Control*, the claims at issue here are reasonably susceptible to Hologic’s construction. Based on (1) the words of the claims themselves, (2) the specification, and (3) the prosecution history as understood by one of ordinary skill in the art, “claim 1 can and should be interpreted as the patentees intended,” *Ortho-McNeil*, 520 F.3d at 1363, thereby “preserv[ing] to the patentee his actual invention.” *McClain v. Ortmyer*, 141 U.S. 419, 425 (1891).

### **E. Claims 1 And 8 Claim Operable Inventions**

When claim 1 is properly construed claims 1 and 8 define operable inventions. Claim 1 reads:

An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:

an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;

a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.

'142 Patent, 8:61-9:6. When claim 1 is properly understood by one of ordinary skill in the art to mean the apparatus volume is a three-dimensional geometric solid composed of the expandable outer surface, the claimed inventions are operable.<sup>5</sup> Under this construction, the expandable outer surface constitutes an apparatus volume (i.e., "defines" it) that is "configured" to have both a volume "to fill an interstitial void" and a surface to "define an inner boundary of the target tissue." A radiation source can thus be "disposed completely within" the volume that fills the interstitial void and "spaced apart from" the surface that defines the inner boundary. One exemplary embodiment of this is shown in Figure 1, reproduced above. *See* '142 Patent, 4:27-30 ("Affixed to the tubular body 12 proximate the distal end 28 thereof is an outer spatial volume 30 defined by an outer polymeric film barrier 32 that is appropriately spaced from the radioactive source 24.") Moreover, this is one of the embodiments that the inventors actually invented, and expressed in their claim language.

#### IV. CONCLUSION

SenoRx's Motion must be denied. First, SenoRx, the party bearing the burden of proving invalidity by clear and convincing evidence has failed to present *any evidence* in support of its Motion. This alone merits its denial. Second, under the proper claim construction, SenoRx is not entitled to judgment as a matter of law because claims 1 and 8 define operable inventions.

Dated: June 4, 2008

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HOLOGIC, INC., CYTYC  
CORPORATION and HOLOGIC LP

<sup>5</sup> SenoRx proffers only the inoperability of claim 1 as a justification for its attempt to invalidate claim 8. Therefore, Hologic will only address claim 1.